K122242

510(k) Summary

DEC 5 2012

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: July 24, 2012

Device Name

Proprietary name: Elecsys CA 15-3 II CalCheck 5
Common name: CA 15-3 II CalCheck 5
Classification: 21 CFR 862.1660, Single (specified) analyte controls (assayed and unassayed)
Product Code: JJX

Predicate device

The Elecsys CA 15-3 II CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys CA 19-9 CalCheck 5 (K101365).

Device Description

The Elecsys CA 15-3 II CalCheck 5 is a lyophilized product consisting of CA 15-3 in equine serum matrix (Level 1) or human serum matrix (Levels 2-5). During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

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Intended use

The Elecsys CA 15-3 II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CA 15-3 II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. For in vitro diagnostics use only.

Comparison Table

The table below compares Elecsys CA 15-3 II CalCheck 5 with the predicate devices, Elecsys CA 19-9 CalCheck 5 (K101365).

Characteristic	**Elecsys CA 15-3 II CalCheck 5 (Candidate)**	**Elecsys CA 19-9 CalCheck 5 (K101365)**	**Elecsys CA 15-3 CalSet (K001468)**
Intended Use	The Elecsys CA 15-3 II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CA 15-3 II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. For in vitro diagnostics use only.	The Elecsys CA 19-9 CalCheck 5 is an assayed control for the use in calibration verification and for use in the verification of the assay range established by the Elecsys CA 19-9 reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	Elecsys CA 15-3 CalSet is used for calibrating the quantitative Elecsys CA 15-3 assay on Elecsys 1010 or 2010 immunoassay systems.
Analyte	CA 15-3	CA 19-9	CA 15-3
Matrix	Human serum, equine serum (Level 1)	Human Serum	Human Serum
Levels	Five	Same	Two
Format	Lyophilized	Same	NA
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, and then mix gently by inversion.	Same	The calibrators are supplied ready for use in bottles that are compatible with the system. The calibrators should only be left on the analyzers during calibration at 20-25°C. After use, close the bottles as soon as possible and store at 2-8°C. Because of possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed.
Stability	Unopened: Store at 2-8°C until expiration date Opened: 20-25°C: 4 hours	Same	Unopened: Same Opened: Twelve weeks at 2-8°C On the analyzers: Up to five hours in total

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Performance Characteristics

The Elecsys CA 15-3 II CalCheck 5 was evaluated for value assignment and stability. See the following sections for details.

Value Assignment

Value assignment testing was conducted and must pass pre-defined acceptance criteria. For each Elecsys CA 15-3 II CalCheck 5 lot manufactured, the CalChecks are run in duplicate on at least three E170 analyzer measuring cells. The assigned value of each CalCheck is defined as the median value obtained over at least 6 determinations (duplicate runs on at least 3 analyzer measuring cells) of the respective CalCheck. The target value for each CalCheck is the median value obtained over at least 6 determinations of the respective CalCheck. The assigned range is calculated as ±21% of the assigned value for levels 2 through 5, while level 1 is assigned as a value ≤ 2.5 U/mL. The % CV is 5% for levels 2 through 5. The label states that each laboratory should establish appropriate acceptance criteria when using this product for its intended use.

To ensure the values assigned using the master platform are transferrable and valid for the other instrument platforms, the same value assignment procedure is performed on the Elecsys 2010, **cobas e** 411, **cobas e** 601, and **cobas e** 602 analyzers. The assigned values obtained on the additional analyzers are compared to those obtained on the MODULAR ANALYTICES E170. The median value obtained on the four additional analyzers must be within 10% of the master platform assigned value (10% for between analyzer platform tolerances). After this acceptance criterion is met, the assigned values from the master platform are deemed valid for the MODULAR ANALYTICS E170, Elecsys 2010, **cobas e** 411, **cobas e** 601, and **cobas e** 602 immunoassay analyzers.

Stability

Real-time and accelerated stability tests were conducted to establish the shelf-life and open-vial claims.

Open-Vial Stability After Reconstitution:
Real-time testing was performed and the data support the package insert claim that reconstituted Elecsys CA 15-3 II CalCheck 5 is stable up to 4 hours at 20-25°C.

Shelf-Life Stability:
The accelerated stability testing performed at 35°C supports an initial shelf-life claim of 18 months at 2-8°C. Real-time testing at 2-8°C is on-going to support a claim of 36 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Date: December 5, 2012

Roche Diagnostics
C/O Ms. Edie Eads
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, IN 46250-0416

Re: k122242
Trade/Device Name: Elecsys CA 15-3 II CalCheck 5
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: November 02, 2012
Received: November 05, 2012

Dear Ms. Eads:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k122242

Device Name: Elecsys CA 15-3 II CalCheck 5

Indication for Use:

The Elecsys CA 15-3 II CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys CA 15-3 II reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. For in vitro diagnostics use only.

Prescription Use __X____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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